

BACKGROUND

The Court has already set out the factual and procedural background of this case in its summary judgment order. Defendant Damon S. Arney is the owner and president of AMC and ICA, separate companies engaged in the business of handling “food,” as the FDCA defines the term. The Court has concluded that based on the undisputed evidence adduced at summary judgment by the United States, each Defendant is liable for its own individual violations of the Act. More specifically, the Court considered the history of FDA inspections at the facilities of both AMC and ICA and held that each company had violated the Act. Moreover, the Court found that Defendant Arney is individually liable in his capacity as president and owner of each enterprise.

The only remaining issue is what form of relief the Court should grant the government, particularly whether there exists a likelihood of future violations. With respect to this issue, the following additional facts are not in dispute for purposes of summary judgment.¹ In June 2010 Defendant AMC acquired the building at 1270 Warford Street in Memphis, Tennessee. (Defs.’ Statement of Add’l Facts ¶ 4.) The building has over 38,000 square feet of space which includes sufficient room for the offices of both AMC and ICA. (*Id.*) AMC occupies approximately 1,000 square feet of separate offices from ICA. (*Id.*) AMC does not store any of its inventory at the Warford Street location. (*Id.*)² Additionally, ICA occupies approximately 20,000 square feet of

¹ Defendants included a statement of additional facts with their response brief, most of which are arguably material to issue of the likelihood of future violations. Defs.’ Counter-Statement of Disputed Facts (D.E. # 35-27). For that reason the Court declined to address these additional facts in its summary judgment order, *see also* Order Granting in Part, Denying in Part Pl.’s Mot. Summ. J. 44 n.84, Aug. 24, 2012 (D.E. # 49), and finds it appropriate to take them up now.

² As the Court stated in its summary judgment order, AMC no longer takes physical possession of the goods it sells or processes the goods in any way for its customers. (Arney Decl.

warehouse space and there is another 7,500 square feet of warehouse space that is unoccupied and listed for lease. (Defs.' Statement of Add'l Facts ¶ 4.) When AMC purchased the building on Warford Street, neither AMC nor ICA could move into the space immediately because they needed to make improvements to the physical plant in order to make it appropriate to process food. (*Id.* ¶ 5.)

AMC and ICA expended significant resources ensuring that the Warford facility underwent considerable construction and restoration work. (*Id.* ¶ 6.) AMC hired M.A. Pratt Construction Company to perform the renovations. (*Id.*) The construction firm spent several months - from the summer of 2010 until early 2011 - renovating the facility to accommodate the move of the AMC offices and ICA to the Warford Street facility. (*Id.*)³ According to Defendants, many of the improvements were made in an effort to address the concerns previously noted by the FDA inspectors at the Farmville and Huron locations and to ensure compliance with the FDCA as well as FDA regulations. (*Id.*)

Furthermore, ICA has engaged a number of sanitation consultants and pest control consultants in recent years to assist in modifying operations and procedures to address various issues related to sanitation, good manufacturing practices and pest control, and to ensure compliance with the FDCA as well as FDA Regulations. (*Id.* ¶ 7.) As part of this effort, ICA has improved its pest control practices, inspection procedures for merchandise being purchased and stored (including truck

¶¶ 6, 7.) Rather, when AMC makes a sale, the goods ship to the customer from one of three independent warehouse facilities. (*Id.* ¶ 7.) Furthermore, in light of its new operations model, AMC terminated all of its employees except for one individual who was reassigned to ICA. (*Id.*)

³ Defendants have attached a list of these improvements to their summary judgment briefing. Pratt Decl., ex. B-1 (D.E. # 35-5).

and pallet inspections), employee training with regard to sanitation practices, pest control and good manufacturing practices, and have worked with experts and consultants to prepare procedures and guidelines for sanitation, Hazard Analysis and Critical Control Points (“HACCP”) food safety system, and food sanitation as well as pest control measures. (*Id.*) ICA does not currently possess any of the dry goods that were ever housed at the Huron Avenue facility. (*Id.* ¶ 8.)⁴

On June 22, 2011, the Tennessee Department of Agriculture (“TDA”) conducted an inspection of AMC and ICA at the Warford Street facility. (*Id.* ¶ 9). The inspection was conducted by Joe McCool, who has been employed by the TDA for 38 years. (*Id.*) The TDA and McCool regularly conduct contract-inspections on behalf of the FDA. (*Id.* ¶ 10.) During both TDA inspections and FDA-contract sanitation inspections, the policies and procedures regarding the inspections are essentially the same and inspect for substantially the same deficiencies. (*Id.*) Plaintiff denies Defendants’ contention that the TDA’s inspection and process was the equivalent of an FDA inspection. The United States has adduced evidence that unlike an FDA inspection, the TDA inspectors did not collect samples for testing. (Tucker Decl. ¶ 43 (D.E. # 26-2)). The areas inspected during both TDA and FDA-contract inspections include, but are not limited to building structure (walls, doors, windows, floors, and seals), actual or potential contamination (insects and rodents), handling practices (products, tools, and equipment), and storage facilities and practices (racks, bins, and pallets). (Defs.’ Statement of Add’l Undisputed Facts ¶ 10.)

The June 22, 2011 inspection of the Warford Street facility was done according to TDA’s

⁴ There is also evidence in the record that “ICA has no dry storage goods in the Warford Street facility that were in stock when FDA conducted its inspection in November 2010” with the exception of some oils or resin, which have no expiration date, and chemicals, which have extended expiration dates and were not cited by the FDA in their inspection. Pratt Decl. ¶ 11 (D.E. # 35-4).

standard practices and procedures. (*Id.* ¶ 11.) The TDA inspection concluded that the Warford Street facility was structurally sound, appropriately set-up, safe, clean, and free of contamination (including a lack of both rodents and insects). (*Id.* ¶ 12.) Specifically, TDA found no violations as to AMC, and only a single, minor violation as to ICA. (*Id.*) The minor violation was limited to a scoop for dry ingredients which needed to be covered. (*Id.*) No response was required for this violation as ICA immediately remedied the violation in TDA’s presence. (*Id.*) The TDA inspector concluded that he had no evidence from which to believe that ICA or AMC is likely to commit future violations of the FDCA at the Warford Facility. (*Id.*) The TDA inspection was conducted on June 22, 2011, approximately seven months after the most recent FDA inspection, which occurred on November 11, 2010. (*Id.* ¶ 13.) The Warford Street facility had undergone significant improvements during the time period between the FDA and TDA inspections. (*Id.*)

In addition to the TDA inspection, Defendants have engaged multiple sanitation consultants and pest control consultants to inspect the Warford Street Facility. (*Id.* ¶ 14.) In the spring of 2011, the Warford Street facility had three independent audits. (*Id.*) In February 2011, the American Institute of Baking (“AIB”) performed an independent audit, finding no indication that ICA was out of compliance with the federal or state regulations. (*Id.*)⁵ On March 15, 2011, consultant Mike Holcomb conducted an inspection, which noted only minor structural and sanitation

⁵ The government contests this statement as well as the statement at ¶20 because Defendants have offered for support only Arney’s declaration, which would constitute inadmissible hearsay. The government’s objection is noted. Rule 56(c)(4) requires that a declaration used to oppose a motion must “set out facts that would be admissible in evidence” Fed. R. Civ. P. 56(c)(4). However, there is no indication that the conclusions of the AIB audit or the Food Safety International audit “cannot be presented in a form that would be admissible in evidence.” Fed. R. Civ. P. 56(c)(2). It is sufficient that the audits could ultimately be presented to the finder of fact in an admissible form. *Alexander v. CareSource*, 576 F.3d 551-558-59 (6th Cir. 2009).

recommendations for ICA's operations. (*Id.*) On April 27, 2011, ICA obtained a food safety audit from Food Safety International, Inc., John R. Williams, Jr., a Food Safety auditor. (*Id.*) The standards utilized to measure compliance included the FDCA, FDA regulations concerning current good manufacturing practices ("cGMP"), the Global Food Safety Initiative Standards, Kodex's principles for HACCP, Military Sanitary Standards, the Food Allergen Labeling & Consumer Protection Act of 2004, and the U.S. Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). (*Id.*) Based upon those standards, the April 2011 audit gave ICA an overall food safety level rating of "excellent." (*Id.*)

As discussed at summary judgment, the United States has the burden to prove that each Defendant has violated the Act and that there is a likelihood of future violations.⁶ While the Court has granted the government judgment as a matter of law on each Defendant's liability, the parties disagree sharply on this second issue, particularly on the significance of the subsequent remedial measures Defendants have undertaken since the last FDA inspection. Defendants maintain that there is no likelihood of future violations based on the fundamental changes Arney has made to the way AMC and ICA conduct their operations. The United States asserts that each Defendant's history of violations alone suggests that future violations are more than likely. The Court determined that additional arguments from the parties would aid the Court in reaching its decision and convened a hearing on the limited issues of the likelihood of future violations and the proper scope of injunctive relief, if any.

⁶ Order Granting in Part, Denying in Part Pl.'s Mot. Summ. J. 43, Aug. 24, 2012 (D.E. # 49).

The government argued at the injunction hearing that the evidence of each Defendant's past violations is simply the best indication of the likelihood of future violations. The United States emphasized that Defendants have a proven track record of violations, demonstrating that they cannot achieve compliance with the law on their own. The government further argued that Defendants' promises of improvement ring hollow in light of their inability to correct the same recurring issues over time. As a result, the oversight of the Court and the FDA is required. According to the United States, the relief it seeks against Defendants is not punitive but sufficient to ensure each Defendant's future compliance with the FDCA. The terms of the proposed injunction would not shut down Defendants' businesses, only correct their current violations and bring them into compliance going forward.

The United States went on to highlight reports in the record from ICA's new pest control company tending to show that insects and rodents continued to be found in and near the new Warford Street facility. As recently as December 2011, pest control records indicate the presence of pests despite all of the corrective measures Defendants claim to have taken.⁷ As for AMC, the government argued that Defendants have presented no plans for oversight of AMC's new third-party warehousing providers. The United States asserted that AMC and Arney have a continuing duty to ensure that their independent contractors comply with the law. The government claimed that it does not know whether AMC is still semi-processing its goods for customers and if so where this

⁷ The government also argued that some of the records contained inconsistencies about the pest activity on the premises of the Warford Street facility. The government contends that even with these apparent inconsistencies in the reports, ICA's manager Douglas Pratt signed off on the paperwork without catching the errors and questioning the pest control company. According to the United States, this reflects a basic lack of oversight and attention to detail, reinforcing the government's view that ICA is not committed to compliance.

processing occurs. Plaintiff cautioned that without an injunction nothing would prevent Arney from going back to AMC's old business model of receiving and shipping food at its own premises. In short, the government argued that an injunction was necessary to bring Defendants into compliance, particularly once "the light of litigation" is no longer shining on their activities.

Defendants countered that the government had failed to show a likelihood of future violations based on the record currently before the Court. Defendants stressed the distinct nature of each business and the types of products each company deals in to make the point that a "one size fits all" injunction is inappropriate in this case. Defendants have made a number of investments to improve their operations since the last FDA inspection in November 2010, changes the government has no evidence to controvert. For example, AMC has shuttered its Farmville Road warehouse and processing facility and transitioned into a purely bulk trade business. Under its new operational model, AMC leases warehouse space in New Jersey and stores no goods in Memphis. In the event a customer needs additional processing of a product, Arney identifies a third-party vendor and contracts the work out. According to Defendants, these changes "remedy any concern" the Court or the FDA might have about past problems at the Farmville Road facility.⁸ Concerning the third-parties with whom AMC contracts, Defendants stated that Arney has no interest or ownership in those entities. Defendants claim that the New Jersey warehouses where AMC stores its inventory is FDCA-compliant. Based on this evidence, Defendants argued that the government had failed to carry its burden for injunctive relief against AMC.

⁸ Defendants added that all of the equipment at the Farmville Road facility is listed for sale and is currently stored there.

Defendants next argued that an injunction against ICA should not issue. ICA has now moved all of its operations to the newly re-furbished Warford Street facility, a property Arney purchased in June 2010 before this litigation commenced. Defendants claimed that the last FDA inspection of the facility occurred while construction was still ongoing.⁹ Since then, three separate inspections of Warford Street, one by the American Institute of Baking, one by Food Safety International, and one by a consultant hired by ICA, have reported no violations. Similarly the Tennessee Department of Agriculture conducted an inspection in June 2011 and found no violations. ICA's plant manager Doug Pratt has completed training in sanitation and safety requirements and now conducts monthly training with ICA employees. As for the evidence of continued pest activity, Defendants simply respond that no business can be entirely perfect and that ICA now has systems in place to address inevitable problems.¹⁰ Defendants contended that any questions the government might have about the current state of Defendants' operations arise from the fact that the government has not conducted another inspection in almost two years. Defendants argued that Arney "has seen the light" and undertaken these measures and others to avoid future violations of the Act. No precedent exists to grant injunctive relief under the circumstances presented in this case. Should future violations actually occur, however, Defendants stated that the government has a number of options including *in rem* seizures, suits for injunctive relief, and even criminal prosecution. Defendants, and

⁹ Defendants also claimed that the rodent excreta pellets discovered during the last FDA inspection actually fell off pallets of goods brought from ICA's Huron Avenue location.

¹⁰ Defendants pointed out that a number of large companies including Schwans, Kelloggs, and Tyson have all received warning letters recently from the FDA about violations. Defendants also contested the inconsistencies the government noted in the pest control company's reports, suggesting that the government may have misinterpreted the information contained in the record.

particularly Mr. Arney, have significant incentive to avoid such sanctions. Therefore, the Court should not issue an injunction.

In its rebuttal, the government addressed a number of Defendants' positions. The Tennessee Department of Agriculture's 2011 inspection was not as comprehensive as the normal FDA protocol in that, for example, the state inspectors did not collect samples for laboratory analysis. In the government's words, "TDA does what they do." The United States returned to the record evidence showing that pest activity continued at the new Warford Street facility throughout 2011 and that the pest management solutions recommended by Defendants' consultant were already in place even before the last FDA inspection in November 2010. The government further insisted that AMC address its third-party storage providers in any plans for future pest control. Finally, the government explained it had attempted to negotiate different outcomes with Defendants, which ultimately did not work out. The Court should not penalize the government for not conducting subsequent, post-litigation inspections.

STANDARD OF REVIEW

As previously set out at summary judgment, the government's burden is to show that "cause" exists to issue an injunction for Defendants' individual violations of the FDCA.¹¹ The Court previously explained that separate consideration of each corporate Defendant is required at the remedies stage. As such, the Court must analyze the likelihood of AMC committing future violations as a separate and distinct issue from the likelihood of ICA committing future violations. Moreover, in the event the Court finds a likelihood of future violations as to a corporate Defendant,

¹¹ Order Granting in Part, Denying in Part Pl.'s Mot. Summ. J. 43.

the Court will then need to consider what form of injunctive relief is appropriate under the circumstances as a remedy against that Defendant.

ANALYSIS

I. Defendant AMC

First, the Court holds that the government has shown a likelihood of future violations as to AMC but only in the event that AMC should resume operations similar in nature and kind to those it once conducted at its Farmville Road facility. The evidence before the Court shows that AMC has changed its business significantly, moving away from food handling and processing to simple distribution. In fact, it appears that AMC no longer takes physical possession of its inventory at all. Rather AMC leases warehouse space in other states where its products are stored until AMC makes a sale. While it is true that AMC altered its business some time after the last FDA inspection of the Farmville Road operation, the government has failed to adduce any evidence that AMC's new operations are likely to result in future violations of the Act. Moreover, the government's proposed injunction does not take into account the obvious change in circumstances. The fact remains that the government has shown that AMC and Arney have violated the FDCA and its regulations on more than one occasion.

Under the circumstances, the Court concludes that the following injunctive relief is appropriate as to AMC and Mr. Arney in his capacity as owner and president of the company. AMC, Arney, each and all of AMC's officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently

restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court as follows:

(A) AMC and Arney shall store or cause goods for sale by AMC to be stored only in facilities registered with FDA as food storage facilities, as required by 21 U.S.C. § 350d. AMC and Arney shall notify FDA in writing within fourteen (14) calendar days of the entry of this order of any location where AMC's products constituting "food" are held for sale. Thereafter, AMC and Arney shall have an ongoing duty to provide FDA with written notice of any location where AMC's products constituting "food" are held for sale within fourteen (14) calendar days of the goods' first arrival at the holding location. All notices under this paragraph shall include the name of the party with whom AMC has contracted for warehouse space, the physical address of the facility where the goods are held, and the facility's FDA registration number.

(B) AMC and Arney shall notify FDA in writing within fourteen (14) calendar days of the entry of this order of any third-party company, vendor, contractor, or other entity which engages in the handling and/or processing of food sold by AMC. Thereafter, AMC and Arney shall have an ongoing duty to provide FDA with written notice, identifying any such third-party which engages in handling and/or processing food sold by AMC within fourteen (14) calendar days of AMC entering into an agreement for the third-party's services. All notices under this paragraph shall include the name of the third-party, the business address of the party, and the physical address of the facility where the handling and/or processing occurs.

(C) AMC and Arney shall notify FDA in writing at least thirty (30) calendar days after any lease or sale of AMC's Farmville Road facility, identifying the name of the buyer or lessee of the property and the date of sale or lease.

II. Defendant ICA

Next, the Court holds that the government has shown a likelihood of future violations as to ICA based on past violations reported at the Warford Street facility but only to a limited extent. The FDA inspection in November 2010 reported violations in the facility involving the presence of insects and rodents, and the Court has granted summary judgment to the government on ICA's violations. At the same time, the Court finds that the government has failed to show cause for much of the injunctive relief it seeks. The record shows that ICA has finalized its refurbishment of the Warford Street facility, passed a series of audits for food safety and pest management, developed and implemented a pest control program, and currently utilizes an employee training program in food safety. To the extent that the government seeks an injunction to compel Defendants to take these same steps, the injunction is not warranted and the relief sought is moot. Therefore, the Court holds that the United States has failed to carry its burden to show that all of the relief it seeks is necessary to prevent future violations of the FDCA and its regulations.

Nevertheless, the Court concludes that the following injunctive relief is appropriate as to ICA and Mr. Arney in his capacity as owner and president of the company. ICA, Arney, each and all of ICA's officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court as follows:

(A) ICA and Arney shall provide a certified copy of ICA's current Sanitation Standard Operating Procedures ("SSOPs") to FDA within fourteen (14) calendar days from the entry of this order. Thereafter, ICA and Arney shall continuously and effectively implement, on an ongoing

basis, the written SSOPs at the Warford Street facility, including but not limited to making written copies of the sanitation control program available and accessible to all employees, agents, and contractors of ICA. In the event that ICA determines that the SSOPs need to be revised or amended, ICA and Arney shall provide proposed changes to FDA in writing at least twenty-eight (28) business days prior to their planned implementation.

(B) ICA and Arney shall provide paid monthly training to all officers, agents, employees, and contractors working on the premises of the Warford Street facility with regard to sanitation practices, pest control and good manufacturing practices. The training should include topics covered in video training materials produced by the American Institute of Baking (“AIB”), or their equivalent. ICA and Arney must maintain records to document that each officer, agent, employee, and contractor has completed the training, including the results of any testing administered.

(C) ICA and Arney shall maintain pest control services for the Warford Street facility at all times. Pursuant to their pest control service, ICA and Arney shall obtain written reports and records from their pest control provider, documenting the type of measures taken against pests, the location of any stations or traps installed for pests, and the presence of any pest activity in and around the facility. ICA and Arney shall forward copies of all such reports and records to FDA within fourteen (14) calendar days of receiving the same from their pest control provider.

(D) ICA shall maintain copies and produce for immediate inspection any and all of the following records (as they are more fully defined in the declaration of Douglas Pratt [D.E. # 35-4]):

- (1) pest control records,
- (2) truck inspection reports,
- (3) retention samples taken from every lot of every product received at the Warford Street facility for a period of one year from taking delivery

of the lot, (4) pallet inspection reports, (5) employee training records, (6) daily blend reports, and (7) current SSOPs.

III. Injunctive Relief as to All Defendants

In addition to the specific injunctive relief granted as to each Defendant, the following provisions will apply generally to all Defendants as well as each and all of AMC and/or ICA's officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships):

(A) For purposes of this order, the term "food" shall have the meaning defined in 21 U.S.C. § 321(f).

(B) Defendants shall provide notice of this order in the following manner:

(1) Within fourteen (14) calendar days of the entry of this order, Defendants shall provide a copy of this order, personally, or when necessary, by certified mail, return receipt requested, to each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships);

(2) post a copy of this order on a bulletin board in the employee common area at the Warford Street facility and ensure that the order remains posted so as it remains in effect;

(3) hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this order.

(4) Within twenty-one (21) calendar days of the entry of this order, Defendants shall provide FDA with an affidavit attesting to their compliance with the notice provisions of this paragraph.

(B) Within fourteen (14) calendar days from the date of employment of each new employee hired by AMC or ICA after the entry of this order, Defendants shall provide the new employee with a copy of this order, personally, or when necessary, by certified mail return receipt requested.

(C) Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in ownership, name, or character of either business entity, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business. Defendants shall provide any prospective successor or assign with a copy of this Order at least thirty (30) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within fourteen (14) calendar days of providing a copy of this Order to any prospective successor or assign.

(D) Defendants shall address all communications with FDA required under this order to Director, New Orleans District Office, Food and Drug Administration, 404 BNA Drive, Building 200, Suite 500, Nashville, TN 37217, and shall reference this civil action by case name and civil action number in such communications.

(E) Except as provided in the foregoing provisions of this order, the parties shall bear their own costs and attorneys' fees in this action.

(F) This Court retains jurisdiction over this action for the purpose of enforcing or modifying this order and for the purpose of granting such additional relief as there may exist cause to grant. If any Defendant violates this order or commits material violations of the FDCA and/or its

implementing regulations after entry of this order, the United States may petition this Court for further relief. Should the Court conclude that any Defendant has violated this order or committed material violations of the Act and/or its implementing regulations, the Court may award the government additional relief against that Defendant, including but not limited to criminal and/or civil penalties; reasonable attorneys fees, costs, and expenses associated with bringing the subsequent enforcement proceeding; and the reasonable costs and expenses associated with the inspection that revealed the violations.

IT IS SO ORDERED.

s/ S. Thomas Anderson
S. THOMAS ANDERSON
UNITED STATES DISTRICT JUDGE

Date: November 8, 2012.